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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/975,514	10/12/2001	Matthew D. Putnam	09531-076001	9763

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EXAMINER	
MELSON, CANDICE C	
ART UNIT	PAPER NUMBER
3732	

DATE MAILED: 10/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/975,514	Applicant(s) PUTNAM, MATTHEW D.
	Examiner Candice C. Melson	Art Unit 3732

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 July 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-24,28-30,33-35* is/are rejected.

7)☒ Claim(s) *25-27,31 and 32* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☒ The proposed drawing correction filed on *20 July 2003* is: a)☒ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1) Claims 1-10,14-17,30 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Border (USPN 5,935,127) in view of Matthews (USPN 5,779,705). Border discloses a method for treatment of a fracture in long bone which comprises "an intramedullary rod 10" which "includes a joint segment 13 separated from a diaphyseal segment 15 by a middle segment 14. Matthews teaches tines "with smooth shanks 212,262 which are an easy sliding fit in predrilled holes in the nail 20, 25" (column 2, lines 23-25). As to Claim 2, Border discloses a channel 16 extends between ends 13 and 15 so that rod 10 can be positioned in a bone with the aid of a conventional guide pin. A slotted shaped opening 17 extends through metallic portion 12 adjacent joint segment 13. In this embodiment, slot 17 has a width just larger than the diameter of an intended fastening screw. Those skilled in the art would appreciate that other suitable fasteners could be substituted for the described screw (s)" (column 2, lines 29-41). "In order to attach the diaphyseal segment of the rod 10 it includes a pair of fastener bores 22". In addition, "although rod 10 is shown in FIG. 1 as not having a bow, those skilled in the art would appreciate that bowed rods could be used to better fit the internal contours of any suitable long bone within which rod 10 is being positioned". With respect to Claim 3, "a portion of channel 16 adjacent joint segment 13 is threaded in order to facilitate the attachment of tools during the

implantation procedure" (column 2, lines 49-52). Figure 4 shows a generally round or oval cross section of the entire intramedullary rod. Furthermore with respect to Claims 4-6 and 9-10, Matthews discloses "a surgical intramedullary rod". "Typically, the rods may be manufactured in varying lengths and diameters from a biologically inert material which is sterilized and has appropriate mechanical strength. The section of the nail is typically tubular with an outer diameter of approximately 12 to 16 mm" (column 3, lines 35-41). With respect to Claims 14-16, Border discloses "guide 30" which "is attached to the internal threads 20 of the proximal end of the rod 10 and mated to notches 18 as shown in FIG. 2" (column 3, lines 12-14). Furthermore, guide 30 of Border is mounted to the rod by insertion of a portion of the guide into the channel in the rod (see col. 2, lines 49-52). Regarding Claim 30, because a drilling guide is disclosed there is inherently a drill bit. With respect to Claim 35, Matthews' tines may be press-fit tines as shown in Fig. 1 and the head portion would also act as the stop because the tine could not advance beyond this portion of the tine. It would have been obvious to one of ordinary skill at the time of the invention to incorporate the tines and variable lengths and diameters as taught by Matthews into the kit disclosed by Border in order to provide the appropriate dimensions for easier, and an overall more secure insertion in the bone.

2) Claims 1-3, 7-8, 14-20 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moehring (USPN 4,846,162) in view of Matthews. Moehring discloses a method for bone fracture fixation including a "rod 10" which is "dimensioned to substantially conform to the shape of the medullary canal of bone". "A first transverse aperture 20 extends through opposing wall portions of rod 10 at a second, opposite end 13 thereof spaced a first predetermined longitudinal distance X from a second end 13 of the rod. An optional second

transverse aperture 22 extends through opposing wall portions of rod 10 spaced a second predetermined longitudinal distance Y from bight portion 16" (column 3, lines 25-32). The second end is the joint segment and the bight portion is the diaphyseal segment. Matthews teaches, tines "with smooth shanks 212,262 which are an easy sliding fit in predrilled holes in the nail 20, 25" (column 2, lines 23-25). Moehring further discloses, with respect to Claims 3, 18-19 and 23, "channel 26 is threaded for the outermost several centimeters at the joint segment. With respect to Claims 7 and 8, figure 3 shows a generally round cross-section of the intramedullary rod. Furthermore, "a guide pin 40" is disclosed. Figure 4 shows that the guide pin is inserted and mounted to the first mounting section at the diaphyseal segment. In anticipation of Claim 16, "a guide 52 is attached to second end 13 of rod 10 by a threaded shaft 58 that extends through a hollow body 54 and threadably engages the threads on inner wall surface 26 (FIG. 5)" (column 4, lines 42-46). With respect to Claim 17, the tines disclosed by Matthews have a shaft and are mounted to the rod at the second mounting section. "A drill bit 64" is disclosed in anticipation of Claim 30. It would have been obvious to one having ordinary skill to incorporate the tines as taught by Matthews into the intramedullary rod kit disclosed by Moehring in order to provide a means for gripping the bone surrounding the intramedullary rod for more secure fixation.

3) Claims 1-3, 7-8, 14-15,17-20 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Durham et al. (USPN 6,106,528) in view of Matthews. Durham et al. disclose a modular intramedullary fixation system which "intramedullary rod 13". "The intramedullary rod 13 includes an elongated body 15 consisting, in general, of a hollow shaft, and having a joint segment 17 and a diaphyseal segment 19. Joining these two segments is a middle segment. The

joint segment 17 of the body 15 of the intramedullary rod 13 has a transverse aperture therethrough" (column 8, lines 35-39). Matthews teaches tines "with smooth shanks 212,262 which are an easy sliding fit in predrilled holes in the nail 20, 25" (column 2, lines 23-25). Durham et al further disclose, "as indicated above, the body 15 preferably consists of a hollow shaft and the channel 25 preferably extends completely through the body 15, from the joint segment 17 to the diaphyseal segment 19 thereof as will now be now more apparent to those skilled in the art" (column 8, lines 43-47). Durham et al also show "channel 25" having a "threaded portion 39". Figure 4 shows a generally round cross-section of the rod. Figure 2 shows that the rod has a curved configuration similar to the curvature of the intramedullary canal. Regarding Claims 14 and 15 Durham et al disclose a "guide 301" which is used "to orient drill guides 389". Because there a drill guide 301 disclosed by Durham et al, inherently there is also a drill bit, thus anticipating Claim 30. With respect to Claim 17, it is further disclosed that "a pair of joint segment bone screws S are inserted horizontally through the lateral bone cortex of the femur F, through the aperture 21" (column 18, lines 41-43). Figures 39 and 41 show the screws S. The screw S is considered to be a tine. It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate the tines as taught by Matthews into the intramedullary fixation system in order to provide a more secure fixation with the bone surrounding the intramedullary rod.

4) Claims 1, 4-8, and 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cole et al. (USPN 6,221,074) in view of Matthews. Cole et al. disclose an "intramedullary kit 10". "Although kit 10 is shown implanted in a human femur 12, kit 10 could also be used in conjunction with other bones as would occur to one skilled in the art, including but not limited

to, the tibia, humerus, radius, ulna, and fibula. Rod 14 includes a joint segment 14a and a diaphyseal segment 14b. Rod 14 defines a longitudinal centerline axis L1 running along the length of the rod 14 between joint segment 14a and diaphyseal segment 14b. Matthews teaches tines "with smooth shanks 212,262 which are an easy sliding fit in predrilled holes in the nail 20, 25" (column 2, lines 23-25). Cole et al further disclose, for application to an adult femur, joint segment 14a preferably has a diameter of about 11-13 millimeters. The diameter of the remainder of rod 14 may vary depending upon the requirements of the fixation procedure and the surgeon's preference. While rod 14 has a generally circular cross-section, other suitable shapes are also contemplated as would occur to one skilled in the art. Furthermore, with respect to Claims 11-13, figure 1 shows the first mounting section channels 24a and 24b are threaded and receive bone screws 22a and 22b, respectively. Both screws shown are bicortical bone screws. It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate the tines as taught by Matthews into the intramedullary fixation system disclosed by Cole et al in order to provide a more secure fixation with the bone surrounding the intramedullary rod.

5) Claims 28-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Border in view of Matthews in further view of Allen et al. (USPN 5,979,658). Border and Matthews disclose the claimed invention except for written instructional information and an instructional video. It would have been obvious to one of ordinary skill in the art at the time the invention was made to include written instructions and an instructional video into any kit since it was known in the surgical art that physicians and/or patients might require training on use of

products. For example, in the kit disclosed by Allen et al., an instructional video and written instructions are provided.

6) Claims 33-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Border in view of Matthews in further view of Cachia et al. (US 2001/0049529). Border and Matthews disclose an intramedullary rod kit as stated in Claim 1 however, they do not disclose a kit where the diaphyseal surface of the rod comprises dimples and there is a therapeutic coating either on the rod, tensioning device or tine. In a similar art, Cachia et al. disclose a bone fixation device with an elongated body where a "micropitted or otherwise textured surface" is provided "on the anchor components" (paragraph 0094). Furthermore, Cachia et al disclose "the anchor components of the invention may contain one or more bioactive substances, such as antibiotics, chemotherapeutic substances, angiogenic growth factors, substances for accelerating the healing of the wound, growth hormones, antithrombogenic agents, bone growth accelerators or agents, and the like" (paragraph 0093). It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate a textured surface and bioactive coating, as taught by Cachia et al. to the intramedullary rod disclosed by Border in order to enhance osteoincorporation and to contribute to the healing of the injury in addition to providing mechanical support, respectively.

Allowable Subject Matter

Claims 21-27 and 31-32 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments with respect to claims 1-34 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Candice C. Melson whose telephone number is (703) 305-8128. The examiner can normally be reached on 8:00am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Shaver can be reached on (703) 308-2582. The fax phone numbers for the

organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Candice C. Melson
October 6, 2003

Cary E. O'Connor
Primary Examiner